

prompt, safe, and effective disposal methods while providing effective controls against the diversion of controlled substances.

Subpart A—Disposal of Controlled Substances by Registrants

§ 1317.05 Registrant disposal.

(a) *Practitioner inventory.* Any registered practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

(1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier pick-up or pick-up by other registrants at the registrant's registered location to: The registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located.

(i) The request shall be made by submitting one copy of the DEA Form 41 to the Special Agent in Charge in the practitioner's area. The DEA Form 41 shall list the controlled substance or substances which the registrant desires to dispose.

(ii) The Special Agent in Charge shall instruct the registrant to dispose of the controlled substance in one of the following manners:

(A) By transfer to a registrant authorized to transport or destroy the substance;

(B) By delivery to an agent of the Administration or to the nearest office of the Administration; or

(C) By destruction in the presence of an agent of the Administration or other authorized person.

(5) In the event that a practitioner is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the practitioner to dispose of such substances, in accordance with subparagraph (a)(4) of this section, without prior application in each instance, on the condition that the practitioner keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals. The Special Agent in Charge may place such conditions as he/she deems proper on practitioner procedures regarding the disposal of controlled substances.

(b) *Non-practitioner inventory.* Any registrant that is a non-practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

(1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier or pick-up at the registrant's registered location to: The registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Promptly transport that controlled substance by its own means to the registered location of a reverse distributor, the location of destruction, or the registered location of any person authorized to receive that controlled substance for the purpose of return or recall as described in paragraph (b)(3) of this section.

(i) If a non-practitioner transports controlled substances by its own means to an unregistered location for destruction, the non-practitioner shall do so in

accordance with the procedures set forth at § 1317.95(c).

(ii) If a non-practitioner transports controlled substances by its own means to a registered location for any authorized purpose, transportation shall be directly to the authorized registered location and two employees of the transporting non-practitioner shall accompany the controlled substances to the registered destination location. Directly transported means the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur.

(c) *Collected controlled substances.* Any collector in lawful possession of a controlled substance acquired by collection from an ultimate user or other authorized non-registrant person shall dispose of that substance in the following ways:

(1) *Mail-back program.* Upon receipt of a sealed mail-back package, the collector shall promptly:

(i) Destroy the package in accordance with subpart C of this part using an on-site method of destruction; or

(ii) Securely store the package and its contents at the collector's registered location in a manner consistent with § 1301.75(c) of this chapter (for practitioners), or in a manner consistent with the security requirements for Schedule II controlled substances (for non-practitioners) until prompt on-site destruction can occur.

(2) *Collection receptacles.* Upon removal from the permanent outer container, the collector shall seal it and promptly:

(i) Destroy the sealed inner liner and its contents;

(ii) Securely store the sealed inner liner and its contents at the collector's registered location in a manner consistent with § 1301.75(c) of this chapter (for practitioners), or in a manner consistent with § 1301.72(a) of this chapter (for non-practitioners) until prompt destruction can occur; or

(iii) Securely store the sealed inner liner and its contents at a long-term care facility in accordance with § 1317.80(d).

(iv) *Practitioner methods of destruction.* Collectors that are practitioners (*i.e.*, retail pharmacies and hospitals/clinics)

shall dispose of sealed inner liners and their contents by utilizing any method in paragraph (a)(1), (a)(2), or (a)(4) of this section, or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier pick-up or by distributor pick-up at the collector's authorized collection location.

(v) *Non-practitioner methods of destruction.* Collectors that are non-practitioners (*i.e.*, manufacturers, distributors, narcotic treatment programs, and reverse distributors) shall dispose of sealed inner liners and their contents by utilizing any method in paragraph (b)(1), (b)(2), or (b)(4) of this section, or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier or by distributor pick-up at the collector's authorized collection location for destruction. Freight forwarding facilities may not be utilized to transfer sealed inner liners and their contents.

§ 1317.10 Registrant return or recall.

(a) Each registrant shall maintain a record of each return or recall transaction in accordance with the information required of manufacturers in § 1304.22(a)(2)(iv) of this chapter.

(b) Each registrant that delivers a controlled substance in Schedule I or II for the purpose of return or recall shall use an order form in the manner described in part 1305 of this chapter.

(c) Deliveries for the purpose of return or recall may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that advance notice of the return is provided and delivery is directly to an agent or employee of the person to whom the controlled substance is being returned.

§ 1317.15 Reverse distributor registration requirements and authorized activities.

(a) Any person that reverse distributes a controlled substance shall be registered with the Administration as a reverse distributor, unless exempted by law or otherwise authorized pursuant to this chapter.